BY ORDER OF THE SECRETARY OF THE AIR FORCE

AIR FORCE INSTRUCTION 44-105

6 NOVEMBER 2014

Medical

THE AIR FORCE BLOOD PROGRAM

COMPLIANCE WITH THIS PUBLICATION IS MANDATORY

ACCESSIBILITY: Publications and forms are available for downloading or ordering on the e-Publishing website at **www.e-publishing.af.mil.**

RELEASABILITY: There are no releasability restrictions on this publication.

OPR: AFMOA/SGBL

Certified by: AF/SG3
(Brig Gen Charles E. Potter)

Supersedes: AFI44-105, 11 January 2012

Pages: 30

This publication provides the standardized procedures for management and operation of the Air Force Blood Program (AFBP) in alignment with requirements set forth by the agency formerly known as the American Association of Blood Banks (AABB), the ASBP, the College of American Pathologists (CAP), Health Affairs (HA), and the Food and Drug Administration (FDA).

This Air Force Instruction (AFI) implements Air Force Policy Directive (AFPD) 44-1, *Medical Operations*, Department of Defense Instruction (DoDI) 6480.4, F044 AF SG J, Air Force Blood Program, *Armed Services Blood Program (ASBP) Operational Procedures*, Department of Defense Directive (DoDD) 6000.12E, *Health Services Support*, and Air Force Manual (AFMAN) 44-111_IP, *AABB Standards for Blood Banks and Transfusion Services*. It applies to all individuals assigned to Air Force (AF) blood missions, including AF Reserve and Air National Guard personnel upon mobilization. This AFI may be supplemented at any level, but all supplements must be routed to the Air Force Blood Program Division (AFBPD), also known as Air Force Medical Operations Agency (AFMOA)/SGBL, for coordination prior to certification and approval. Refer recommended changes and questions about this publication to the AFBP using AF Form 847, *Recommendation for Change of Publication.* Refer recommended changes and questions about this publication to AFBPD using AF Form 847, Recommendation for Change of Publication. Route AF Forms 847 from the field through the appropriate functional chain of command. Ensure that all records created as a result of processes prescribed in this publication are maintained in accordance with AFMAN 33-363, *Management of Records*, and disposed of in accordance with the Air Force Records Disposition Schedule (RDS) located in the Air Force Records Information Management System (AFRIMS). This instruction directs the collection and maintenance of information subject to the Privacy Act of 1974. Patient and donor information collected is also subject to compliance with the Health

Insurance Portability and Accountability Act (HIPAA) of 1996. Forms affected by the Privacy Act have an appropriate Privacy Act statement. The authorities to waive wing/unit level requirements in this publication are identified with a Tier number (T-0, T-1, T-2, T-3) following the compliance statement. See AFI 33-360, *Publications and Forms Management*, for a description of the authorities associated with the Tier numbers. Submit requests for waivers through the chain of command to the appropriate Tier waiver approval authority, or alternately, to the Publication OPR for non-tiered compliance items.

SUMMARY OF CHANGES

The revision of this publication updates the new Surgeon General (SG) signature block, formalizes the medical consultant role to the AFBPD and notes that the value of blood credit expenditure from civilian collections credits does not equal charges for one blood product. On Attch 2, Aviano Medical Group (MDG) was added and the MDG number for Langley Air Force Base (AFB) was updated. Tiering has been completed IAW AFIS directives and AFI 33-360.

Chapter 1

PROGRAM OVERVIEW, ROLES, AND RESPONSIBILITIES

1.1. Overview. This publication provides the standardized procedures for management and operation of the Air Force Blood Program (AFBP) in alignment with requirements set forth by the agency formerly known as the American Association of Blood Banks (AABB), the ASBP, the College of American Pathologists (CAP), Health Affairs (HA), and the Food and Drug Administration (FDA). The AFBP provides safe, cost-effective, quality blood products and services in support of the DoD's wartime and peacetime medical missions. The AFBPD ensures that collection, manufacturing, storage, distribution and transfusion of blood products to military personnel adhere to the current Good Manufacturing Practices (cGMPs) and regulations published by the FDA in Title 21 of the Code of Federal Regulations (21 CFR), Parts 200-299 and Parts 600-680, and the standards of national accrediting agencies. The AFBP operates per direction of the Air Force Surgeon General (AF/SG) by authority granted under Biologics License Number 610, issued by the FDA.

1.2. Program Organization. The primary focus of the AFBPD is to provide leadership, direction and guidance for all elements of the AFBP in support of expeditionary and peacetime medical missions. The AFBP is an integral part of the ASBP. The ASBP is under the responsibility of the Assistant Secretary of Defense for Health Affairs. The Secretary of the Army is the Department of Defense (DoD) Executive Agent for the ASBP. The ASBP is an integrated blood products system composed of the Military Services' and Combatant Commands' blood programs, and is coordinated by the Armed Services Blood Program Office (ASBPO). This program provides blood products to DoD Military Treatment Facilities (MTFs) for both peacetime and wartime use. The readiness posture of the program is maintained through an active voluntary donor program, blood collection, blood product manufacturing, quality assurance, logistics, and transfusion training programs. The program also actively participates in joint exercises and responds to homeland defense contingencies and public health emergencies when directed by government authorities.

1.3. AFBP Elements. The AFBP is composed of various operational, manufacturing and shipping elements. The AFBP elements include Blood Donor Centers (BDCs), Transfusion Services (TSs), Continental United States (CONUS) blood depots/distribution centers titled Armed Services Whole Blood Processing Laboratories (ASWBPLs), Expeditionary Blood Transshipment Centers (EBTCs), Expeditionary Blood Support Centers (EBSCs), and Frozen Blood Product Teams (FBPTs). Each element contributes to a tri-service blood distribution system that supports MTFs in CONUS, outside CONUS (OCONUS to include U.S. territories Alaska, Hawaii, Puerto Rico and Guam) and at overseas locations (facilities operating in foreign locations) during peacetime and wartime. All CONUS and OCONUS facilities are registered or licensed with the FDA and maintain accreditation by the AABB. All overseas facilities must be registered with the FDA and are highly encouraged to follow AABB standards.

1.4. Responsibilities.

1.4.1. The **Assistant Secretary of the Air Force for Manpower and Reserve Affairs (SAF/MR)** serves as an agent of the Secretary of the Air Force and provides guidance,

direction, and oversight for all matters pertaining to the formulation, review, and execution of plans, policies, programs, and budgets addressing the AFBP. **SAF/MR** will:

1.4.1.1. Provide funds, facilities, and support personnel, as required, to maintain the BDCs and the ASWBPLs.

1.4.1.2. Fund transportation of AF-collected and processed blood products and incidental expenses associated with their delivery to the first CONUS destination.

1.4.1.3. Provide, as the DoD Executive Agent for the ASWBPLs, EBTCs, EBSC and FBPT appropriate support personnel, facilities, and budgetary resources, as required to maintain at least two ASWBPLs in active status.

1.4.2. The **AF/SG** will:

1.4.2.1. Serve as the authorized agent for the AF Biologics License Number 610, issued by the FDA. Exercise control over all matters relating to compliance with FDA requirements as detailed in 21 CFR Parts 200-299 and 600-680. Ensure all AFBP elements gain FDA registration or licensure, as appropriate, and comply with FDA regulations.

1.4.2.2. Ensure appropriate action is taken to correct and prevent recurrence if the FDA issues a Form 483, *Inspectional Observations*, to an AFBP element.

1.4.2.3. Ensure the FDA's Director, Office of Compliance, Center for Biologics Evaluation and Research (CBER) receives notification within 24 hours in the event of a transfusion-related fatality or when the post-transfusion cause of death is unknown and could possibly be related to transfusion.

1.4.2.3.1. Ensure FDA/CBER receives notification of reportable biological product deviations.

1.4.2.3.2. Provide for continuing education programs for clinical laboratory officers and quality assurance (QA) staff to ensure they are current in cGMPs and matters of FDA compliance and regulation.

1.4.2.4. Appoint the Chief, AFBPD from candidates provided by the Chief Consultant to the Surgeon General for Medical Laboratory.

1.4.2.5. May delegate FDA reporting responsibilities by appointing the Chief, AFBPD to serve as an alternate authorized agent to the FDA.

1.4.3. **AFMOA** will:

1.4.3.1. Support the AFBP and ensure adequate resources are available to meet blood missions.

1.4.3.2. Provide consultation to MAJCOMs for any blood-related matters via the AFBPD.

1.4.3.3. Ensure blood program funds received from the ASBP are properly distributed. Ensure that MTFs with blood services funding requirements identify and request appropriate AF Military Health Service (MHS) funding.

1.4.4. The **Chief, AFBPD** will:

1.4.4.1. On behalf of the AF/SG, manage the AF Biologics License Number 610, issued by the FDA. Coordinate AF policies to ensure compliance with AABB, ASBP, FDA, HA and other regulatory or accrediting agencies, to include fatality reporting, deviation reporting and coordination of the infectious disease lookback program.

1.4.4.2. Serve as authorized agent to the FDA and appoint AFBPD staff as authorized agents, as appropriate.

1.4.4.3. Serve as executive agent for coordination and management of all AF blood matters including operational, research, training and quality assurance issues. Provide operational guidance to MAJCOMS, MTFs and readiness sections. Assist in determining training and manning requirements for enlisted laboratory technicians and laboratory officers serving in operational blood missions.

1.4.4.4. Serve as liaison between MTFs and the FDA. The AFBPD is the only agency authorized to interact with the FDA (except when the MTF is undergoing on-site FDA inspections). All FDA license/registration applications and biological product deviations must be coordinated through, approved by and submitted by the AFBPD (T-2).

1.4.4.5. Serve as the consultant to the Manpower and Equipment Force Packaging Responsible Agencies for blood-related Unit Type Codes, Allowance Standards and pilot units. Ensure readiness functions are appropriately identified, staffed and funded.

1.4.4.6. Perform regulatory evaluations of the AF FDA-licensed and registered facilities to provide guidance and ensure compliance with all applicable regulations and standards (T-2).

1.4.4.7. Direct the actions of the quality assurance managers to ensure compliance with regulations and accreditation standards. Guide MTFs in appropriate investigation, corrective action and submission of all FDA-reportable deviations.

1.4.4.8. Monitor any reports of suspected transfusion-transmitted diseases submitted to the AFBPD as required by the FDA reporting system and lookback regulations.

1.4.4.9. Establish AF blood product quotas for DoD contingencies and identify blood mobilization requirements.

1.4.4.10. Coordinate the activities of AF BDCs to meet the ASBPO quota requirements and monitor blood distribution network effectiveness during peacetime and wartime.

1.4.4.11. Ensure AFBP elements appropriately fund the peacetime component of their blood missions using the Program Objective Memorandum (POM) process at their attached MTF.

1.4.4.12. Contact the ASBPO to identify and obtain appropriate funding when the AFBP mission is expanded due to war, contingency or emergency.

1.4.4.13. Provide the ASBPO with accurate requirements for forecasting and sourcing the types and quantities of blood products to be procured for peacetime use, homeland defense, wartime and contingencies.

1.4.4.14. Compile AFBP quality assurance statistics for process improvement initiatives, and coordinate with the ASBPO to establish program performance metrics and standards.

1.4.4.15. Assist in the development, deployment and maintenance of information technology initiatives in support of the AFBP and ASBP.

1.4.4.16. Supervise the Directors, ASWBPL-East and ASWBPL-West.

1.4.5. The **Medical Consultant, AFBPD** will:

1.4.5.1. Serve a consultative role to the ASBPO and AFBPD on donor acceptability, review of FDA reports, updating deferral lists and readiness issues. May also serve as medical advisor on DoD committees and other Federal Committees.

1.4.5.2. Be a transfusion medicine trained Pathologist, preferably board certified in transfusion medicine.

1.4.6. Installation Commanders will:

1.4.6.1. Encourage donors at the frequency and in the quantity necessary to enable AF BDCs to meet peacetime and contingency needs for blood products. Encourage cooperation between subordinate commanders to support the AFBP mission and to minimize interruption of work and training schedules while soliciting blood donors during normal duty hours.

1.4.6.2. Ensure DoD-affiliated BDCs, where available, have priority access to donors over civilian blood collecting organizations in order to meet DoD healthcare requirements (T-2).

1.4.6.3. Establish Memorandum of Understanding (MOU) with all civilian blood collection agencies that are granted access to DoD donors on military installations in accordance with (IAW) HA Policy 04-015, *Revised Policy Regarding Standardization of Infectious Disease Reporting Requirements for Civilian Blood Agencies Collecting Blood on Military Installations, at Military Leased Facilities or Aboard Ships*, HA Policy 04-019, *Revised Policy Regarding Civilian Blood Collections on Military Installations, Leased Facilities, and Aboard Ships*, and this instruction. (T-0 Reference HA Policy 04-015, 04-019)

1.4.6.4. Provide necessary support to enable the ASBP, BDCs, and/or civilian blood collection agencies with MOUs to perform blood drives (T-3).

1.4.6.5. Ensure the Military Personnel Section (MPS) provides the requesting military BDC with a base personnel roster of active component members by unit and ABO and Rh blood type (T-3). Refer to Paragraph 2.1.3 for further information.

1.4.6.6. Appoint in writing, a motivated officer, senior NCO, or civilian employee (GS-7 or higher) who is able to dedicate the time to serve as the Base Blood Program Officer (BBPO) (T-3). For bases with AF BDCs, the BDC recruiter will serve as the BBPO. The BDC recruiter does not require appointment.

1.4.7. The **BBPO**:

1.4.7.1. Maintains a program of continuing donor education and motivation to recognize people for their donations. Encourage donation by establishing unit competitions and donor recognition programs, coordinated through unit commanders (T-3).

1.4.7.2. Develops a system with points-of-contact for each installation unit to provide donors for installation-sponsored blood drives (T-3).

1.4.7.3. Updates the installation commander, at least annually, on donor program activities and unit blood collection statistics (T-3).

1.4.7.4. Ensures that MOUs are accomplished with each civilian agency collecting donors on the installation (T-3).

1.4.7.5. Works in consultation with the MTF laboratory when developing a MOU.

1.4.8. The **MTF Commander**:

1.4.8.1. Ensures compliance with AABB, ASBP, FDA, HA and other accrediting agency standards, to include fatality reporting, deviation reporting and the infectious disease lookback program (T-1).

1.4.8.2. Takes the necessary corrective actions to ensure compliance with FDA regulations and notify the AFBPD of any unresolved problems (T-1).

1.4.8.3. Appoints a qualified Medical Director to direct the local TS and/or BDC(T-1).

1.4.9. The **AFBP Elements**:

1.4.9.1. Comply with directives, regulations and standards of AABB, ASBP, FDA, HA and other accrediting agencies to include fatality reporting, deviation reporting and the infectious disease lookback program (T-2).

1.4.9.2. Develop and maintain a QA program (T-2).

1.4.9.3. Contact the AFBPD prior to any communication with the FDA. Sites are not authorized to directly communicate with the FDA (T-1).

1.4.9.4. Ensure the AFBPD receives notification in the event of a transfusion-related fatality or when the post-transfusion cause of death is unknown and could possibly be related to transfusion. Notification to the AFBPD must occur as soon as possible and no later than 24 hours after discovery (T-1).

1.4.9.5. Initiate all infectious disease lookback functions as required by the FDA. Possible, suspected and confirmed cases of transfusion-transmitted disease requiring lookback investigation will be reported to the AFBPD as a biological product deviation (T-1).

1.4.9.6. The appropriate peacetime funding is requested through the MTF's POM process in alignment with the AF POM schedule. BDCs and ASWBPLs will request appropriate funding through the MTF to which they are attached. Coordination of funding for expanded missions due to contingency or emergency will be managed through the AFBPD, who will in turn contact the ASBPO to identify appropriate funding.

1.4.9.7. Prepare for continuous operation at the maximum tasking noted in AFI 44-118, *Operational Procedures for the Armed Services Blood Program Elements* (T-3).

1.4.9.8. BDCs should be prepared to supply existing inventory stock immediately (less than 24hrs) upon identified contingency need (T-3).

1.4.9.9. If applicable, participate in the ASBP frozen blood program as directed and funded.

1.4.9.10. Establish minimum, target and maximum blood product inventory levels (T-3).

1.4.10. The **Inventory Manager**:

1.4.10.1. Monitors blood inventory levels to keep inventory near the established target level (T-3).

1.4.10.2. Maintains account with the DoD CONUS Blood Management Tool (BMT) (T-3).

1.4.10.3. Procures and distributes excess blood products for routine day-to-day MTF use via methods that offer the greatest overall advantage to the AF (T-3).

1.4.10.4. Prior to distributing products to non-DoD facilities, the Inventory Manager (T-3):

1.4.10.4.1. Establishes support arrangements with other AF TSs.

1.4.10.4.2. Posts excess inventory to the BMT for AF disbursement for one day.

1.4.10.4.3. Posts excess inventory to the BMT for DoD disbursement for one subsequent day.

1.4.10.4.4. Makes available any remaining excess not distributed via above methods to the VA or through civilian blood exchange programs.

1.4.10.5. Due to the short shelf-life of platelets, these products may be distributed outside of the above priority list if necessary.

1.4.10.6. Note: If a facility has a MOU whereby blood products are provided in exchange for human resources, excess inventory may be distributed to the facility providing human resources at a higher priority if necessary to meet the terms of the MOU.

1.4.11. The **Quality Assurance** (**QA) unit** will:

1.4.11.1. For BDCs, be separate from operational responsibility and not supervised by the BDC management.

1.4.11.2. For TSs, be separate from operational responsibility, as much as possible.

1.4.11.3. Be responsible for the QA program to ensure compliance with AABB, ASBP, FDA HA and other accrediting agencies, to include fatality reporting, deviation reporting and the infectious disease lookback program (T-3).

1.4.11.4. Retain authority to cease production of blood products if problems with cGMP are identified.

1.4.11.5. Submit annual QA report to the AFBP (T-2).

1.4.12. The **ASWBPLs** will:

1.4.12.1. Receive and maintain a contingency reserve of blood products and act as a central repository for forward shipment of blood products to operational units.

1.4.12.2. Perform ABO and Rh confirmation testing on Red Blood Cell (RBC) units.

1.4.12.3. Pack, ice and prepare blood products for shipment to the theater.

1.4.12.4. Prepare for continuous operation at the maximum tasking noted in AFI 44-118.

1.4.12.5. Distribute excess blood products to the Service Blood Programs, to Veterans Affairs (VA) facilities or other locations as directed by ASBPO via the Chief, AFBPD.

1.4.12.6. Provide support to exercises (real-world blood support and simulated blood), as directed by the ASBPO via the AFBPD.

1.4.12.7. When directed and funded by the AFBPD, maintain equipment, supplies and an adequate number of trained personnel for freezing, deglycerolization and training purposes in support of the ASBP frozen blood program.

1.4.12.8. Provide daily inventory reports, weekly compliance reports and other reports as directed to the AFBPD.

Chapter 2

BLOOD DONOR CENTER OPERATIONS

2.1. Overview. BDCs serve vital peacetime and wartime missions supporting the MHS with blood products in CONUS and worldwide. The three AF BDCs are located at Keesler AFB, Mississippi, Lackland AFB, Texas, and Wright Patterson AFB, Ohio. Blood will only be collected from United States personnel to include military members, DoD civilians or contractors, or beneficiaries.

2.1.1. **Voluntary Donations.** All blood donations will be voluntary and will comply with FDA and AABB requirements. The AF encourages its employees to volunteer as blood donors. A civilian employee may be excused for a maximum time of four hours to support volunteer blood donation IAW AFI 36-815, *Absence and Leave*. Military commanders may authorize time-off incentives for active duty personnel.

2.1.2. **Donor Nourishment.** Refreshments (such as cookies and fruit juice) should be provided to donors to minimize adverse reactions to blood donation. Subsistence items should be purchased through Medical Logistics using Operation and Maintenance (O&M) funds at sites with attached AF BDCs. Donor nourishment items must not be purchased with medical subsistence funds. **Note:** Civilian organizations operating blood drives on base will furnish their own nourishment items for donors.

2.1.3. **Donor Recruitment.** Recruiting should target specific blood types and products to meet local and contingency requirements. Random collections should be avoided in order to reduce outdate rates and avoid waste of government resources for collection, testing and distribution. Close coordination must be maintained with installation command personnel to provide enough donors to ensure that specific numbers and blood types are provided on request. BDCs should request active duty alpha rosters from the MPS as needed.

2.1.4. **Donor Motivation.** Reasonable incentives and recognition, such as t-shirts, coffee mugs, or coins, may be offered to encourage continued donations (Reference FDA Compliance Policy Guide Sec. 230.150, *Blood Donor Classification Statement, Paid or Volunteer Donor).* **Note:** Civilian organizations will furnish their own donor incentive items.

2.1.5. **Aircrew.** Aircrew members who donate blood (200 mL or more) will be disqualified from flying for a minimum of 72 hours IAW AFI 48-123, *Medical Examinations and Standards*. This restriction includes donation of whole blood, plasmapheresis and plateletpheresis.

2.2. Product Distribution. Products manufactured by AF BDCs will be distributed according to section 1.4.9. in this instruction and in the following descending priority:

2.2.1. Contingency requirements, including support of ASBPO-levied quotas.

2.2.2. MHS requirements at AF MTFs.

2.2.3. MHS requirements at other DoD MTFs.

2.2.4. Requests from other institutions such as VA or Public Health Service.

2.2.5. Other civilian exchange programs.

2.3. Walking Donor Program (WDP). All MTFs should incorporate blood planning in their contingency response plans and determine when a WDP may be required. WDPs are intended for overseas facilities where the local blood supply may not be equivalent to FDA standards, or where the local supplier may not be able to provide enough blood products during contingency situations. The use of blood collected under emergency conditions may be required to save life or limb during mass casualty events or combat operations.

2.3.1. MTFs that identify a need to establish a WDP should coordinate with their respective MAJCOM/SG and Area Blood Program Officer (ABPO) for approval and guidance.

2.3.2. The MTF is responsible for funding the WDP.

2.3.3. To the extent possible, MTFs with WDPs will establish and maintain rosters of pre-infectious disease tested donors (HBsAg, Anti-HBc, Anti-HCV, HCV RNA, Anti-HIV 1/2, HIV-1 RNA, Anti-HTLV I/II, WNV RNA, Syphillis, Chagas) and will repeat prescreening at regular intervals not to exceed 90 days.

2.3.4. When emergency blood collections are required, donors will be selected in the following descending priority:

2.3.4.1. Donors who have been prescreened within the last 90 days with the full panel of FDA-licensed donor infectious disease tests and found to be negative for all tests. **Note:** Any donor with a positive test result will not be listed as an approved, prescreened donor and must not be collected.

2.3.4.2. Donors who report being repeat blood donors in the past and have not been deferred for transfusion-transmitted disease.

2.3.4.3. Donors who have not been prescreened with FDA-licensed tests, nor have been blood donors in the past.

2.3.5. On the day of donation, prospective donors will be screened for eligibility using approved donor history screening protocols and be tested for infectious diseases using ASBPO-approved rapid screening tests. As much as possible, rapid screening tests should be performed before issuing the product.

2.3.6. Whenever emergency blood units are collected:

2.3.6.1. Each unit and its corresponding infectious disease samples will be labeled with a unique donor identification number. The identification number should be International Society of Blood Transfusion (ISBT)-compliant, if possible. Products must be labeled "For Emergency Use Only" IAW 21 CFR Part 610.40(g).

2.3.6.2. The blood samples will be sent to a FDA-licensed donor testing laboratory for retrospective testing.

2.3.6.3. All collection information and the results of all rapid screening and retrospective sample testing will be maintained locally and copies will be provided to the AFBPD.

2.3.6.4. Follow-up notification and counseling will be provided to any donor who tests positive/reactive on either a prescreen, rapid or retrospective infectious disease test. Appropriate medical treatment referrals will be accomplished.

Chapter 3

TRANSFUSION SERVICE OPERATIONS

3.1. Overview. Transfusion of human blood products carries a small, but genuine risk of adverse events and transmission of infectious agents. Alternative interventions, such as the transfusion of synthetic factor concentrates or products that have undergone viral-inactivation procedures (e.g. albumin, other plasma derivatives and substitutes) should be considered for use in lieu of blood products when possible.

3.1.1. **Informed Consent.** Clinicians will accomplish and document informed consent IAW AFI 44-102, *Medical Care Management* (T-1).

3.1.2. **Blood Component Requests.** Standard Form 518, *Blood or Blood Component Transfusion Request Form* (SF 518), suitable Enterprise Blood Management System (EBMS) form or local form shall be completed for each component request. (T-2) **Note:** The SF 518 does not represent the physician's order to transfuse a blood product, but may be used to document the transfusion event within the recipient's medical record.

3.1.3. **MTF Instruction.** Each MTF that operates a TS shall have an MTF instruction (T-3) that establishes and governs the transfusion-related activities in the facility. The MTF policy will address blood component administration to include the use of infusion devices, compatible fluids, ancillary equipment, administration and blood utilization monitoring. Blood administration shall be consistent with the AABB *Circular of Information for the Use of Human Blood and Blood Components*, AABB standards and FDA regulations.

3.1.4. **Transfusion Reaction.** Investigation of suspected transfusion reactions should use AF Form 1224, *Blood Transfusion Reaction Investigation* or an equivalent locally developed form.

3.1.5. **Transfusion-Related Fatality.** The AFBP (DSN 969-9941 or 9928; Commercial 210-395-9941 or 9928) must be notified within 24 hours of a transfusion-related fatality (T-1) or when the post-transfusion cause of death is unknown and could possibly be related to transfusion. The MTF is required to begin a root cause analysis and forward a report to the AFBPD within five calendar days of the event. The MTF will ensure they inform their chain of command to include the MAJCOM/SG office. The AFBPD will inform the AF/SG and submit the final report within seven days of the event to the FDA at the address in Table 3.1.

Table 3.1. AFBP Notification to the Food and Drug Administration.

Method	Contact Details
E-mail	Fatalities2@cber.fda.gov
Telephone/voice-mail	301-827-6220
Fax	301-827-6748, Attn: CBER Fatality Program Manager
Express mail	FDA/CBER Director, Office of Compliance and Biologics Quality Attn: Fatality Program Manager (HFM-650) 1401 Rockville Pike, Suite 200N Rockville, MD 20852-1448

3.2. Inventory Management. Effective management of blood resources is vital to maintaining sufficient blood products to meet all requirements. The TS must efficiently manage and monitor several key areas of control (T-3).

3.2.1. Establish minimum, target and maximum levels of each blood product by blood type and maintain stock levels near the target threshold to ensure maximum coverage with minimum outdating (T-3).

3.2.2. Monitor the inventory levels and expiration dates of all blood products to ensure minimal outdating and minimal loss of blood products (T-3).

3.2.3. Avoid maintaining stock levels above the established target level.

3.2.4. The MTF will monitor and evaluate MTF blood ordering and usage practices in the blood utilization committee or function (T-3).

3.2.5. Establish maximum time periods for holding cross-matched blood. Consider enacting policy to return cross-matched blood units to the general inventory prior to the three day expiration if it appears the patient will not need the blood (T-3).

3.2.6. Establish a maximum surgical blood order schedule (MSBOS) to identify which surgical procedures require only a Type and Screen and which procedures warrant a Type and Crossmatch. The MSBOS should be developed based on historical records of blood use and in coordination with surgical subject matter experts (T-3).

3.2.7. Use the Type and Screen procedure in lieu of Type and Crossmatch in concert with the MSBOS and whenever the likelihood for blood usage is low.

3.2.8. Before discarding outdated blood products and waste byproducts of blood collection (e.g. Recovered Plasma), they should be utilized for training and research, or recovered through Recovered Blood Product (RBP) agreements. Refer to Paragraph 5.3 of this instruction for requirements related to RBP programs.

3.3. Procurement of Blood Products. Procurement methods for routine day-to-day MTF blood product support will be those which offer the greatest overall advantage to the AF.

3.3.1. Unless doing so hinders patient care activities, procurement sources should be used in the following descending priority:

3.3.1.1. AF BDC or MTF sources.

3.3.1.2. Armed Services Blood Program (ASBP) suppliers via the BMT or direct contact.

3.3.1.3. Resource sharing with the VA.

3.3.1.4. Civilian exchange programs or established MOUs that carry credit balances.

3.3.1.5. When above mechanisms are exhausted, purchase products from community sources.

3.3.1.6. ASWBPLs may be contacted to determine availability of excess products. However, as blood products maintained by the ASWBPLs are considered a DoD joint blood inventory for contingency or emergency operations, MTFs should not routinely depend on these inventories to serve as a primary source of blood product support.

3.3.2. Emergent blood procurement is not governed by the above procurement sourcing rules. The life-saving nature of blood products necessitates that there will be times when products will need to be purchased due to urgent needs or special blood attributes.

3.3.3. Inter-facility shipments may be made by commercial transportation with associated expenses charged to the receiving MTF's O&M account.

3.4. Distribution of Excess Blood Products. Excess blood products will be distributed according to section 1.4.10. of this instruction and using the following descending priority list:

3.4.1. Air Force MTFs.

3.4.2. DoD MTFs.

3.4.3. VA.

3.4.4. Exchange for credit with other agencies.

3.4.5. If a facility has a MOU whereby blood products are provided in exchange for other human resources, excess inventory may be distributed to the facility providing human resources at a higher priority if necessary to meet the terms of the MOU.

Chapter 4

REGULATORY AND ADMINISTRATIVE

4.1. Inventory Accountability.

4.1.1. Inventory management processes shall include frequent, documented determinations that all blood components have a proper disposition and that there are no misplaced blood products.

4.1.2. Facilities maintaining an inventory of blood products shall have a policy to reconcile every blood product listed in the EBMS current inventory, line-by-line, with the blood products in physical inventory. TSs and BDCs must accomplish this reconciliation on a monthly basis at a minimum. ASWBPLs must establish inventory control practices and a periodic reconciliation schedule that allows for accurate tracking of products, but are not required to perform a 100% monthly reconciliation.

4.1.3. AFBP elements will also perform a reconciliation of all products in a status of "Issued" or "Quarantined" on a weekly basis at a minimum.

4.1.4. Sites shall utilize reports generated from the EBMS when reconciling blood product inventory.

4.1.5. Discrepancies shall be resolved and documented in a timely manner. Discrepancies that cannot be resolved will be reported to the AFBPD.

4.2. QA Program.

4.2.1. The QA program will address each AABB Quality System Essential as defined in regulatory standards and will include tracking of metrics where possible and applicable.

4.2.2. The QA unit will conduct assessments through surveys, audits and review of FDA deviation and inspection reports. The QA unit will recommend quality improvements to the AFBP element management. The QA unit is responsible for review of all FDA reportable deviations and inspection responses before submission to the AFBPD and will ensure corrective actions are appropriate (T-3).

4.2.3. The QA unit is responsible for suspending blood product production if problems with cGMPs are identified. The QA unit will notify senior management at any point that a patient safety concern is evidenced (T-3).

4.3. Infectious Disease Lookback Program.

4.3.1. Previously donated blood from donors who currently test positive for infectious diseases (e.g. Human Immunodeficiency Virus, Hepatitis B, Hepatitis C, Human T-cell Lymphotropic Virus) must be tracked to inform those recipients of the increased risk of disease. The AFBPD will be the central point of contact for all suspected transfusion-transmitted disease lookback cases.

4.3.2. All facilities that collect, store, ship or transfuse blood products must maintain all blood product collection, transfusion, testing, shipping and/or disposition records to support present and future transfusion transmitted disease lookback issues as required by regulatory agencies (T-3).

4.3.3. Records must be maintained in a manner which provides physical and environmental protection.

4.3.4. AFBP elements will use the approved EBMS to determine disposition of suspect units of blood.

4.4. Non-FDA Compliant Blood Products.

4.4.1. The transfusion of non-FDA compliant blood products may be required to save life or limb during mass casualty events or combat operations. Examples of non-FDA compliant blood products include products collected by a foreign country or products collected under emergency conditions (e.g. using WDPs) and transfused before FDA-approved blood donor tests are completed.

4.4.2. MTFs that engage in the transfusion of non-FDA compliant blood products will have policies in place to comply with recipient notification and follow-up requirements as outlined in HA Policy 10-002, *Policy On the Use of Non-U.S. Food and Drug Administration Compliant Blood Products* (T-0).

4.4.3. All patients who receive non-FDA compliant blood product transfusions must be tracked and tested for evidence of transfusion-transmitted diseases at three, six, and 12 months post-transfusion (T-3). **Note:** Recipients of blood products from ASBPO-determined equivalent countries are exempted from this requirement. Contact the AFBPD for a list of countries currently designated for exemption .

4.5. FDA Licensure and Registration Program.

4.5.1. A MOU between the DoD and the FDA requires each military department, through its SG, to operate its own blood program in accordance with FDA requirements. The MOU requires FDA registration of all military sites maintaining blood products in inventory.

4.5.2. All active BDCs must be licensed by the FDA for each product that is manufactured and shipped interstate (T-2).

4.5.3. The FDA, at their discretion, inspects licensed and registered facilities to monitor compliance with regulations. Facility FDA inspections generally occur every 2-3 years.

4.5.4. Compliance with FDA regulations is required by civil law and provides recognition that AFBP elements operate under nationally accepted standards of blood product quality and safety. FDA licensure allows the AF to freely exchange licensed blood products with military and civilian blood banks across state lines as necessary.

4.6. AABB Inspections.

4.6.1. The AABB accreditation program is a peer review and educational program motivating its members to strive for the highest level of performance in all aspects of donor collection, component manufacturing and transfusion medicine.

4.6.2. AABB accreditation is mandatory for all AF BDC's and CONUS and OCONUS TSs.

4.6.3. AABB accreditation is highly encouraged for all overseas TSs. Overseas TSs should follow AABB standards as closely as possible even if not AABB-accredited.

4.7. Computerization and Information Management.

4.7.1. AFBP elements will use the approved standard EBMS real-time as the system of record to perform all operational processes (T-1).

4.7.2. Utilizing the EBMS real-time maximizes critical safety checks and allows facilities to promptly and accurately track each blood unit and product from creation to final disposition as required by the AABB and FDA.

4.7.3. Each facility must publish a Continuity of Operations Plan (COOP) to be followed whenever the approved EBMS is not available for use (T-2). If the approved EBMS is expected to be unavailable for an extended time, the facility should notify the AFBPD.

4.7.4. Electronic and manual records must be maintained for the time periods established by the AABB and FDA in an environment that provides physical and privacy protection. The records must be retrievable within a reasonable timeframe.

4.8. Required Reports.

4.8.1. AF MTFs that collect, store, ship or transfuse blood must update the ASBPO Operational Data Reporting System (ODRS) monthly, and must submit other reports as requested by the AFBP. The ODRS report will be submitted within 10 duty days from the beginning of each month.

4.8.2. Contact the AFBPD to request access to ODRS.

4.8.3. Each FDA-registered facility must submit an annual QA report to the AFBPD (T-2).

4.8.4. Each FDA-registered facility must review and submit their FDA-registration renewal annually to the AFBPD (T-1).

Chapter 5

SHARING AGREEMENTS AND CONTRACT REQUIREMENTS

5.1. Overview. The main purposes for entering into MOUs are: (1) to earn credits for civilian BDC collections on military installations, (2) to exchange excess or expired blood products and (3) to formalize blood support agreements with other DoD BDCs. Facilities may also establish contracts for blood product purchasing and donor infectious disease testing.

5.2. Civilian BDCs Collecting Blood on Military Installations.

5.2.1. Since the government expends resources (e.g. work-hours and utility/maintenance costs) when civilian blood agencies collect blood in AF facilities or on federal installations, MOUs must include a provision requiring the civilian agency to grant credits per donor collected. The credits can be exchanged for blood products or services, at no cost to the AF, in exchange for access to donors and facilities. Blood products or services obtained through a MOU may be used within the MHS or provided to the VA IAW Paragraph 1.4.10.

5.2.2. Each civilian blood agency must have a MOU in order to collect blood donors on an AF installation. MOUs for civilian blood drives will be coordinated through and approved by the Installation Commander, the BBPO, and the AFBPD (T-0). The civilian collection agency must be registered with the FDA as a legal blood collecting organization.

5.2.3. The base point of contact (POC) should contact the AFBPD early in the MOU process so that guidance, templates and a checklist may be provided.

5.2.4. If more than one civilian blood collecting agency requests access to a military base, the civilian agencies will be granted equal access.

5.2.5. When multiple civilian agencies and/or military BDCs are performing blood drives at an installation, the blood drive schedules must be de-conflicted and priority must be given to the military BDC.

5.2.6. MOUs must include the requirements from HA Revised Policy Letters 04-015 and 04-019. The MOUs do not need to include components of these policies that are already addressed in FDA regulations.

5.2.7. The MOU must be reviewed, approved and signed by the AFBPD. The MOU should be sent to the AFBPD for review prior to routing for official signature.

5.2.8. MOUs should be reviewed and negotiated to obtain the best return rate for the AF. The desired accumulation rate for credit-based MOUs is a ratio of one credit for every five donors collected. Facilities may develop other agreements (e.g. standing blood product shipment or other arrangements) as long as the value to the AF approximates the desired one-to-five ratio.

5.2.9. If MOUs are established on a credit basis:

5.2.9.1. MOUs should address credit management so as to avoid high credit balances.

5.2.9.2. The MOU should attempt to define outlets for credit use to keep the credit balance below a desired level of 500. Refer to Paragraph 3.4 of this instruction for distribution priorities.

5.2.9.3. Credits will only be used to obtain blood products, blood bank reference laboratory services, or autologous/therapeutic collection services.

5.2.10. These MOUs will not be used to barter for equipment, donor recruitment incentives nor education or training expenses.

5.2.11. The MTF will track civilian collection numbers, credits earned, credits used and/or appropriate delivery of standing shipments IAW the agreement and local policy for accountability.

5.2.12. MOUs will be reviewed annually by the BBPO and the civilian agency(-ies) to ensure terms remain acceptable. Documentation of the review should be maintained.

5.3. Recovered Blood Product (RBP) Programs.

5.3.1. RBP programs must be operated under a Memorandum of Agreement (MOA) with the MTF/CC and the AFBPD as signatories.

5.3.1.1. The MOA must include a statement that the facility is not obligated to ship RBPs to the vendor.

5.3.1.2. The MOA should be reviewed annually. During the annual review, the facility should compare the reimbursement rate to industry standard to ensure best value.

5.3.2. The facility will establish and maintain a documented system to track all RBP shipments and appropriate vendor reimbursement.

5.3.3. Vendor payments will be mailed to the BDC or TS. The BDC or TS will deliver the check to the MTF budget office for deposit in the Responsibility Center/Cost Center (RCCC) that generated the funds.

5.3.3.1. When funds are generated by a BDC, the first priority for expenditure should be to support the mission of the BDC through purchase of blood donor incentive items (e.g. t-shirts, coffee mugs, coins).

5.3.3.2. Procurement of donor incentive items is authorized in AFI 41-209, *Medical Logistics Support*.

5.4. Other DoD BDCs Collecting Blood on AF installations.

5.4.1. Army or Navy BDCs should request permission to collect donors on AF installations where regional AF BDCs are not able to collect donors. The request should go through the AFBPD first to ensure the BDC is not adversely competing with a regional AF BDC. Installation Commanders must allow DoD-affiliated BDCs to have priority over civilian blood collecting organizations to meet DoD healthcare requirements. DoD BDCs should coordinate with the local BBPO to de-conflict blood donation schedules.

5.4.2. CONUS MTFs located near Army, Navy or AF BDCs are encouraged to negotiate formal agreements for blood inventory support. When primary blood product support is rendered by another service, the AF base donor population should be made available to the supporting facility. Support agreements must be reviewed and signed by the AFBPD.

5.5. Contracts for Blood Product Purchasing.

5.5.1. Blood product costs specified in the contract should be no greater than the prevailing rates charged in the local community.

5.5.2. When a MTF has a MOU whereby blood credits are accrued for donations by military members, those credits should be expended prior to purchasing blood products from civilian facilities.

5.5.3. Facilities remain accountable to the procurement priorities outlined in Paragraph 3.3 of this instruction.

5.6. Contracts for Donor Infectious Disease Testing.

5.6.1. To support increased economies of scale and overall decreased cost to the AF, before a BDC enters a contract with a civilian laboratory for donor infectious disease marker testing, the contracted cost-per-donor should be compared to the AF donor testing reference laboratory's cost-per-donor (per current published cost-per-donor charge) and also to other civilian laboratories to ensure best value for the AF.

5.6.2. The contracted testing laboratory must be FDA-licensed and AABB-accredited.

5.6.3. The contract should specify the maximum result turnaround time to ensure that collected blood will be available for priority shipment to ASWBPLs or immediate local use.

5.7. Wartime Contract Restrictions. It is not permitted to use contractual or any other arrangements made by individual facilities with civilian sector organizations to provide blood products in support of the emergency, mobilization and wartime blood program unless approved by the AFBPD.

Chapter 6

AFBP READINESS FUNCTIONS

6.1. Overview. The AFBP supports war and contingency blood product requirements. The AFBP also responds to homeland defense contingencies and public health emergencies by supporting civilian authorities when directed by authorized government authorities.

6.1.1. Detailed information related to AFBP readiness operations can be found in DoDD 6480.4 and AFI 44-118.

6.1.2. The Federal Emergency Management Agency created the National Blood Program (NBP) to meet the nation's need for blood, blood components, derivatives and plasma expanders in the event of mobilization or national emergency. AF BDCs will support the NBP and national emergencies when directed by the ASBPO.

6.1.3. The ASBPO is responsible for activation of contingency blood product, equipment and supply procurement contracts when necessary to support increased mission requirements or when the need for blood products exceeds DoD's ability to supply required products.

6.2. Blood Readiness Elements/Functions. Additional details for these functions can be found in AF Tactics, Techniques and Procedures (AFTTP) 3-42.711, *Blood Support Operations*

6.2.1. **BDCs.** BDCs provide blood and blood products in support of peacetime and wartime contingencies. BDCs can collect, manufacture, and ship red blood cells (RBCs); Fresh Frozen Plasma (FFP); Cryoprecipitate; Plasma Frozen within 24 hours of phlebotomy; Apheresis Platelets (APLTs); Apheresis FFP; Apheresis RBCs; and RBCs destined for freezing (FRBC). The BDC is typically a fixed facility under the operational control of the MTF commander at the installation where the BDC is located.

6.2.2. **ASWBPLs.** The ASWBPLs serve as the central receiving and shipment points in CONUS for blood shipments from the BDCs. There are two ASWBPLs, one located at Joint Base McGuire-Dix-Lakehurst, New Jersey (ASWBPL-East) and one at Travis AFB, California (ASWBPL-West), to facilitate blood shipments to MTFs in CONUS and around the world. They are operationally controlled by the AFBPD. The ASWBPLs are capable of expanding operations to meet blood support requirements as necessary.

6.2.3. **EBSCs.** The EBSC is a deployable laboratory team that must be co-located with an AF Theater Hospital (AFTH) or equivalent Joint Deployed Medical Facility (DMF). The EBSC cannot operate in a stand-alone environment. The EBSC team expands blood support capabilities in-theater by providing advanced capabilities in the collection and preparation of blood components to support emergency trauma situations by manufacturing apheresis platelets and fresh whole blood units. The team is operationally controlled by the AFTH/Joint DMF commander.

6.2.4. **EBTCs.** The EBTC provides the capability to receive, store and ship blood products in a theater of operation. EBTCs are normally located at major airfields, with one or more EBTCs assigned within a Combatant Command (COCOM). The EBTCs are operationally controlled by the COCOM Joint Blood Program Officer.

6.2.5. **FBPTs.** The FBPT provides coverage to support the processing of pre-positioned frozen blood stocks. When liquid RBCs are unavailable or below minimum advisable inventory levels, the team thaws and deglycerolizes stockpiled FRBCs for mass casualty, disaster relief or humanitarian assistance operations. The deglycerolized liquid RBCs produced are suitable for transfusion for 14 days and provide the blood units needed to sustain patient care until the liquid pipeline is fully operational.

6.2.6. **Transfusion Services.** TS are part of the MTF's Laboratory operations. During times of disaster or contingencies, TS should follow guidelines outlined in their local medical contingency response plan.

THOMAS W. TRAVIS, Lieutenant General,
USAF, MC, CFS
Surgeon General

Attachment 1

GLOSSARY OF REFERENCES AND SUPPORTING INFORMATION

References

AFI 36-815, *Absence and Leave,* 5 September 2002

AFI 41-106, *Medical Readiness Program Management,* 22 April 2014

AFI 44-102, *Medical Care Management,* 20 Jan 2012

AFI 44-118, *Operational Procedures for the Armed Services Blood Program Element*s, 1 September 2007

AFI 48-123, *Medical Examinations and Standards,* 5 Nov 2013

AFMAN 41-111_IP, *American Association of Blood Banks (AABB), Standards for Blood Banks and Transfusion Services,* 2 May 14

AFPD 44-1, *Medical Operation*s, 1 September 1999

AFTTP 3-42.711, *Blood Support Operations, 19 Apr 2013*

DoD Instruction 6480.4, *Armed Services Blood Program (ASBP) Operational Procedure*s, 13 Aug 2012

FDA Compliance Policy Guide, *Blood Donor Classification Statement, Paid, or Volunteer Donor Sec. 230.150, 1 Nov 2011*

HA Revised Policy 04-015, *Standardization of Infectious Disease Reporting Requirements for Civilian Blood Agencies Collecting Blood on Military Installations, at Military Leased Facilities or Aboard Ships,* 21 June 2004

HA Revised Policy 04-019, *Regarding Civilian Blood Collections on Military Installations, Leased Facilities and Aboard Ships,* 10 August 2004

HA Policy 10-002, *On the Use of Non-U.S. Food and Drug Administration Compliant Blood Products,* 19 March 2010

Title 21, Code of Federal Regulations, Parts 200-299 and Parts 600-680

Prescribed Forms

Standard Form 518, *Blood or Blood Component Transfusion Request,* Sep 92

AF Form 1224, *Blood Transfusion Reaction Investigation,* 20040819 V1

Adopted Forms

AF Form 847, *Recommendation for Change of Publication*

Abbreviations and Acronyms

AABB—Agency formerly known as American Association of Blood Banks

ABPO—Area Blood Program Officer

AF—Air Force

AFB—Air Force Base

AFI—Air Force Instruction

AFBP—Air Force Blood Program

AFBPD—Air Force Blood Program Division

AFBPTM—Air Force Blood Program Technical Memorandums

AFMAN—Air Force Manual

AFMOA—--Air Force Medical Operations Agency

AFPD—Air Force Policy Directive

AF/SG—Air Force Surgeon General

AFTH—Air Force Theater Hospital

AFTTP—--Air Force Tactics, Techniques and Procedures

APLT—Apheresis Platelet

ASBP—Armed Services Blood Program

ASBPO—Armed Services Blood Program Office

ASWBPL—Armed Services Whole Blood Processing Laboratory

BBPO—Base Blood Program Officer

BDC—Blood Donor Center

EBMS—Enterprise Blood Management System

BMT—Blood Management Tool

CAP—College of American Pathologists

CFR—Code of Federal Regulations

cGMP—Current Good Manufacturing Practices

CBER—Center of Biologics Evaluation and Research

COCOM—Combatant Command

CONUS—Continental United States

COOP—--Continuity of Operations Plan

DMF—Deployed Medical Facility

DoD—Department of Defense

DoDD—Department of Defense Directive

DoDI—Department of Defense Instruction

EBSC—Expeditionary Blood Support Center

EBTC—Expeditionary Blood Transshipment Center

FDA—Food and Drug Administration

FFP—Fresh Frozen Plasma

FBPT—Frozen Blood Product Team

FRBC—Frozen Red Blood Cell

HA—Health Affairs

HAF—--Headquarters Air Force

HIPAA—The Health Insurance Portability and Accountability Act

IAW—In Accordance With

ISBT—International Society of Blood Transfusion

MAJCOM—Major Command

MDG—--Medical Group

MHS—Military Health Service

MOU—Memorandum of Understanding

MPS—Military Personnel Section

MSBOS—Maximum Surgical Blood Ordering Schedule

MTF—Military Treatment Facility

NBP—National Blood Program

OCONUS—Outside Continental United States

OVERSEAS—Outside the jurisdiction of the United States

O&M—Operational and Management

ODRS—Operational Data Reporting System

OPLAN—Operation Plan

POC—--Point of Contact

POM—Program Objective Memorandum

QA—Quality Assurance

RBC—Red Blood Cells

RBP—Recovered Blood Product

RCCC—Responsibility Center/Cost Center

RDS—--Records Disposition Schedule

SAF/MR—Secretary of the Air Force for Manpower and Reserve Affairs

SF—Standard Form

SG—--Surgeon General

TS—Transfusion Service

VA—Department of Veterans Affairs

WDP—Walking Blood Program

Terms

AABB—A scientific and technical group, formerly named **American Association of Blood Banks ,** that establishes policy and standardizes procedures for the field of blood banking, including donor collections and transfusion services. Membership and inspections recognize high technical and administrative competence. AABB represents the "gold standard" of quality patient care and customer service.

Air Force Blood Program (AFBP)—The Blood Program operated for the Air Force Surgeon General. This function is located within the Air Force Medical Operations Agency. The Chief, Air Force Blood Program directs the peacetime and wartime operation of the program worldwide.

Area Blood Program Office (ABPO)—A tri-service staffed office responsible for joint blood product management in an assigned geographic area within a unified command.

Armed Services Blood Program (ASBP)—The combined military blood programs of the individual services including unified and specified commands in an integrated blood products support system.

Armed Services Blood Program Office (ASBPO)—A tri-service staffed DoD field operating agency responsible for coordinating the military blood programs and related blood activities of the military departments, the unified and specified commands, various federal, civilian, and allied military agencies. ASBPO is chartered by the DoD to monitor the policies established by the Assistant Secretary of Defense for Health Affairs.

Armed Services Whole Blood Processing Laboratory (ASWBPL)—A tri-service staffed facility that is responsible for receipt and reprocessing of blood products from CONUS blood donor centers, and shipment of these products to designated unified command blood transshipment centers (BTC). The Air Force is the executive agent for all ASWBPLs.

Blood Donor Center (BDC)—Component staffed CONUS agencies responsible for collecting and processing of blood products. Processed blood will be shipped from the BDC to the ASWBPL. BDCs may be collocated within a blood bank.

Food and Drug Administration (FDA)—The FDA Division of Blood and Blood Products establishes blood banking regulations and requirements for use by blood banks involved in interstate commerce (shipping blood and blood products across state lines), and grants licenses to blood banks that comply with those standards. The FDA considers blood as a manufactured drug. The military departments comply with these standards and each service Surgeon General holds an FDA license for the respective service's blood banks.

FDA-Biological Product Deviation— Reportable errors occur when an event takes place during the collection, processing, testing and/or labeling of blood products that affect the safety, purity or potency of the blood product and the blood product was distributed ("distributed" is further defined as "the biological product has left the control of the licensed manufacturer or unlicensed blood establishment").

Fresh Frozen Plasma (FFP)—Plasma is the straw colored liquid obtained when separating red blood cells from whole blood. In peacetime, blood banks freeze and store this product for no more than one year at -18C or colder. For contingencies, military blood banks extend the shelf life to three years.

Joint Blood Program Office (JBPO)—A tri-service staffed office responsible for overall joint blood product management in a unified command theater of operations.

Maximum Surgical Blood Ordering Schedule (MSBOS)—A hospital approved list of recommended blood ordering practices by procedure based on national blood use averages. Adherence to the MSBOS prevents over utilization of limited blood bank resources and better manages blood inventory for when it is truly is needed.

Medical Treatment Facility (MTF)—A facility established for the purpose of furnishing medical and/or dental care to eligible individuals.

Platelet Concentrates (PC)—Platelets are cellular fragments in the blood that assist in blood clotting. Platelet concentrates are separated from whole blood by centrifugation and are stored at room temperature for up to five days with gentle agitation, or at -80C for two years.

Red Blood Cells (RBC)—RBCs are the oxygen carrying component of whole blood. RBCs are separated from whole blood by centrifugation or sedimentation and removal of residual plasma.

Type and Crossmatch—A blood bank procedure to determine the ABO and Rh groups of a patient and the serologic compatibility test with a donor unit of red cells to ensure safe transfusion. A Type and Crossmatch procedure is used when the probability of actual blood usage is high.

Type and Screen—A blood bank procedure to determine ABO and Rh groups of a patient and the antibody screen to determine if the patient has any unusual antibodies that might complicate finding a compatible unit of red blood cells. A Type and Screen procedure is used when the probability of actual blood usage is low.

Overseas—outside the jurisdiction of the United States

Attachment 2

FACILITY FDA REGISTRATION AND LICENSE NUMBERS

Table A2.1. Facility FDA Registration and License Numbers.

UNIT FACILITY	ICCBBA FACILITY CODE	FDA REGISTRATION	FDA LICENSE All use 610
81st Medical Group Keesler AFB MS	W0017	1077548	610
59th Medical Wing Lackland AFB TX	W0013	1677552	610
88th Medical Grp Wright Patterson AFB OH	W0016	1577551	610
ASWBPL-East Joint Base McGuire-Dix-Lakehurst NJ	W0001	2277553	610
ASWBPL-West Douglas B. Kendrick Blood Processing Laboratory Travis AFB CA	W0002	2951520	610
779th Medical Grp Joint Base Andrews MD	N/A	1177549	N/A
673d Medical Grp Joint Base Elmendorf-Richardson AK	N/A	3020816	N/A
60th Medical Grp Travis AFB CA	N/A	2977555	N/A
99th Medical Grp Nellis AFB NV	N/A	2951185	N/A
96th Medical Grp Eglin AFB FL	N/A	1052138	N/A
633d Medical Grp Langley AFB VA	N/A	1177774	N/A
432nd Medical Grp Misawa AB, JA	N/A	9612293	N/A
366th Medical Grp Mountain Home AFB ID	N/A	3024813	N/A
51st Medical Grp Osan AB ROK	N/A	9613030	N/A
48th Medical Grp RAF Lakenheath UK	N/A	9612214	N/A

UNIT FACILITY	ICCBBA FACILITY CODE	FDA REGISTRATION	FDA LICENSE All use 610
374th Medical Grp Yokota AB JA	N/A	9612177	N/A
31st Medical Grp Aviano AB Italy	N/A	9614827	N/A